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510(k) Summary

APR 18 2013

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 (203) 492-5299 (T)
CONTACT PERSON:	Katherine Robertson Senior Specialist, Regulatory Affairs
DATE PREPARED:	April 8, 2013
TRADE/PROPRIETRY NAME:	Endo GIA™ Reload
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
PREDICATE DEVICE(S):	Endo GIA™ Stapler (K061095); Endo GIA™ Stapler, DST Series™ GIA™ Stapler and DST Series™ TA™ Stapler (K111825)
SUBJECT AND PREDICATE DEVICE SIMILARITIES:	The subject and predicate Endo GIA™ Reload place two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the 3.5mm or 4.8mm reload. The 45mm subject and predicate Endo GIA™ Reload is designed for introduction and use through a 12mm trocar sleeve, or larger, with a use of a converter. When using the 60mm subject and predicate Endo GIA™ Reload, it must be inserted into a 15mm trocar sleeve. The subject and predicate Endo GIA™ Reload is used with the Endo GIA™ Universal, Endo GIA™ Universal XL and GIA™ Universal stapler handles. The subject device and the predicate device both are a linear or articulating reload that is attached to a stapler handle. The reload contains staples, a cutting blade, and an anvil which to form the staples. Once the reload is attached to the stapler handle, the trigger on the handle is manually squeezed once to close the anvil in order to clamp the tissue. Once the anvil is fully closed, it securely retains the tissue until it is opened. To fire either the subject or predicate device, a safety must be physically and intentionally disengaged after full clamp-up. Once the safety has been disengaged, the trigger can be squeezed additional times to fire the staples and advance the cutting blade. The number of firing squeezes will increase the cartridge length. The subject and predicate Endo GIA™ reloads are sterilized via ethylene oxide, have 45mm or 60mm staple cartridge lengths, 3.5mm or 4.8mms titanium staples, single use and disposable devices.

SUBJECT DEVICE MODIFICATIONS:	The subject device contains two modifications compared to predicate, the addition suture slots and blunt blades within the anvil and cartridge of the reload. These two minor modifications are the only differences between the subject device and the predicate device. The addition of the suture slots and blunt blades are the result of refurbishment of components from a previously cleared device (K080898). The suture slots within the previously cleared device (K080898) secured suture on the anvil and cartridge to hold reinforcement material. The blunt blades would cut the suture in order to deploy the reinforcement material when the reload is fired. The subject device is refurbished by removing the sutures and tissue reinforcement material. The minor modification of the suture slots and blunt blades do not affect the intended use or fundamental scientific technology of the subject device compared to the predicate device. All other aspects of the subject device and predicate device are the same.
INTENDED USE:	The Endo GIA™ Reload has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.
TECHNICAL CHARACTERISTICS:	The Endo GIA™ Reload is substantially equivalent and has not altered the fundamental scientific technology to the predicate devices with regards to stapling technologies.
MATERIALS:	All components of the proposed device Endo GIA™ Reload are identical to the predicate Endo GIA™ reload (K061095) and a previously cleared device (K080898) and are comprised of materials that are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Design verification and pre-clinical validation studies were conducted to demonstrate that the proposed device Endo GIA™ Reload are safe and effective and perform as intended. Performance testing to support the intended use of this device includes: • In vitro staple formation • Insertion /Removal force • In vivo tissue firing for tissue trauma, knife cut and staple formation • In vivo tissue trauma abrasion • Cytotoxicity Test • ETO Residual Testing – ISO 10993-7:2008 • IR analysis • Passivation (rust and corrosion) – must meet ASTM A967 The result of these tests demonstrates that the proposed device Endo GIA™ Reload is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Covidien
% Ms. Katherine Robertson
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

April 18, 2013

Re: K130717
Trade/Device Name: Endo GIA™ Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 01, 2013
Received: April 03, 2013

Dear Ms. Robertson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130717

Device Name: Endo GIA™ Reload

Indications for Use:

The Endo GIA™ Reload has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130717